Mesh Erosion and What to do

Michelle Y. Morrill, MD
Chief of Urogynecology, TPMG
Director of Urogynecology, Kaiser San Francisco
Assistant Professor, Volunteer Faculty Dept of Ob/Gyn, UCSF

Goals for Today

- Review the history of the use of vaginal mesh in surgery
- Discuss common and serious complications that can arise from vaginal mesh surgery
- Learn about the efficacy of various techniques for approaching vaginal mesh complications

Mesh - Synthetic
- Current standard:
  Polypropylene Type 1 Mesh – Permanent, Monofilament and Macroporous
History

- Stress urinary incontinence (SUI):
  - Variety of abdominal and vaginal surgeries

- 1997 AUA SUI Guidelines recommend retropubic suspensions or (traditional) pubovaginal slings based on 4y outcomes
  *Both are abdominal surgeries with noted morbidity

- 1995 Ulmsten presents the mid-urethral sling (MUS)

SUI continued...

- 2014 Systematic Review of English language RCTs with ≥12m follow-up
  - 127 papers on 49 unique trials

  - MUS equivalent or superior to Burch and pubovaginal sling by subjective, objective and adverse event outcomes

SUI continued...

- 2014 AUGS/SUFU Position Statement on MUS

  "The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women."

Pelvic organ prolapse (POP)
- Vaginal vs. Abdominal approach

1996 Benson et al. RCT avg f/u 2.5y
- Abd 16% repeat surgery
- Vaginal 33% repeat surgery

1997 Olsen et al. 30% of surgeries for POP or UI were repeats

2001 FDA approves mesh device for prolapse
- 510k – based on similarity to mesh for hernia repair

~100 devices developed over the following years

2005-2010
- Erosion 528
- Pain 472
- Infection 253
- Bleeding 124
- Dyspareunia 108
- Organ Perforation 88
- Urinary Problems 80
- Vaginal Scarring/Shrinkage 43
- Neuromuscular Problems 38
- Recurrent Prolapse 32

2008 FDA Public Health Warning
- >1000 reports in 3y of mesh device complications
- Recommend specialized training
- Recommend patient education
History

- POP continued...
  - 2008 FDA Public Health Warning
    - >1000 reports in 3y of mesh device complications
  
- 2011 July FDA Safety Communication
  - >2800 reports in 3y of mesh device complications
  - “Serious adverse events are NOT rare, contrary to what was stated in the 2008 PHN”
  - “Transvaginally placed mesh in POP repair does NOT conclusively improve clinical outcomes over traditional non-mesh repair.”

History

- POP continued...
  - 2011 ACOG/AUGS Committee Opinion
    - “POP vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk”
  - Surgeons need particular training
  - Further research recommendations

History

- POP continued...
  - 2012 FDA mandates postmarket studies (522 studies) for transvaginal mesh devices for POP

Mesh Today

- Multi-incision MUS
  - Gold Standard
- Single incision MUS
- Sacrocolpopexy
  - Abdominal or Laparoscopic approach
- Vaginally placed mesh for POP
Adverse Events

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Erosion</td>
</tr>
<tr>
<td>2</td>
<td>Pain</td>
</tr>
<tr>
<td>3</td>
<td>Infection</td>
</tr>
<tr>
<td>4</td>
<td>Bleeding</td>
</tr>
<tr>
<td>5</td>
<td>Dyspareunia</td>
</tr>
<tr>
<td>6</td>
<td>Organ Perforation</td>
</tr>
<tr>
<td>7</td>
<td>Urinary Problems</td>
</tr>
<tr>
<td>8</td>
<td>Vaginal Scarring/Shrinkage</td>
</tr>
<tr>
<td>9</td>
<td>Neuromuscular Problems</td>
</tr>
<tr>
<td>10</td>
<td>Recurrent Prolapse</td>
</tr>
</tbody>
</table>

1) Mesh erosion in vagina

Intimate partner pain (His-pareunia)

2) Mesh erosion into urinary tract or bowel

3) Dyspareunia or Pelvic Pain

4) Voiding dysfunction
Mesh Erosion in the Vagina

Presentation / Symptoms

- **Symptoms**: vaginal discharge, odor, vaginal pain, dyspareunia, or pain by the sexual partner
- **Often asymptomatic**
  - Wong et al. 56% incidentally found
- **May present years after surgery**

Mesh Erosion Rates

**Vaginal approach prolapse surgery**

- **Cochrane 2013**
  - Anterior mesh 11% erosion
  - Multiple compartments 18% erosion

**Sacrocolpopexy**

- **2.2% Mesh erosion or infection in 52 studies of >5600 patients**
  - mean 26m f/u
- **10% Mesh erosion at 5y in RCT of open sacrocolpopexy (84% f/u)**

---


Maher C et al. Surgical management of pelvic organ prolapse in women. Cochrane Database of Systematic Reviews 2013, Issue 4. Art. No.: CD004014


Mesh Erosion Rates

Mid-Urethral Slings

- 1.4%-2.2% (retropubic & trans-obt)


Mesh Erosion

Risk Factors

- Concomitant hysterectomy
- Vaginal Perforation
- Diabetes
- Smoking
- Age
- Hematoma / Blood transfusion
- Trans-obt > Retropubic


POP Mesh Erosion Management

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation</td>
<td></td>
</tr>
<tr>
<td>Vaginal Estrogen</td>
<td></td>
</tr>
<tr>
<td>Office Excision</td>
<td></td>
</tr>
<tr>
<td>OR Excision</td>
<td></td>
</tr>
</tbody>
</table>


Treatment Efficacy

- Observation: ?30% [1]
- Vaginal Estrogen: 20% [1,2]
- Office Excision: 43% [1]
- OR Excision: 90-95% [1,3]

### POP Mesh Erosion Management

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation</td>
<td>30%</td>
</tr>
<tr>
<td>Vaginal Estrogen</td>
<td>20%</td>
</tr>
<tr>
<td>Office Excision</td>
<td>43%</td>
</tr>
<tr>
<td>OR Excision</td>
<td>90-95%</td>
</tr>
</tbody>
</table>

- OR excision may be best initial approach for symptomatic erosion


### MUS Mesh Erosion Management

- Observation / Vaginal Estrogen
  - TOMUS “most” did not require surgery
  - Vaginal mucosa flap
    - 2/8 exposure recurrence, 8/8 persistent d/c
- Excision


### Mesh Excision Approach

- Small / Focal
  - Dissect overlying epithelium off of mesh
  - ~1cm from edge of erosion

Barber MD. Surgical Techniques for Removing Problematic Mesh. CLINICAL OBSTETRICS AND GYNECOLOGY Volume 56, Number 2, 289-302
Mesh Excision Approach

- Large / Recurrent
  - Remove as much mesh as possible vaginally
  - Know the implant
  - Consider epithelial augmentation with biologic graft

Mesh Erosion or Perforation into Urinary Tract or Bowel

- May happen early or late
- May be asymptomatic or have subtle symptoms
- Increased risk with perforation, even if repaired
  - Tip: Don’t lay mesh over a repaired -otomy

Mesh in Bladder

- Consider options for approach
  - Vaginal
  - Laparoscopic / Laparotomy
  - Cystoscopic with Suprapubic port
- Consider possibility of ureteral involvement
  - Stenting / need for reimplantation
- Detailed counseling
- Appropriate consults
Mesh in Bowel
- Consider options for approach
  - Rectal
  - Vaginal
  - Laparoscopic / Laparotomy
- Detailed counseling
- Appropriate consults

Mesh in Urethra
- Approaches: transvaginal or transurethral
- Optimize visualization
  - Nasal speculum
  - Hysteroscope
  - Grasp ie with Endoclose

Mesh in Urinary Tract or Bowel
Overall: Optimize Surgery
- Multi-Disciplinary Team
- Wait for ideal time for patient
- Very Carefully

Mesh and Pain
Mesh and Pain

- Dyspareunia 9%
  - RF = posterior colporrhaphy and mesh erosion
- Dyspareunia rates are similar for mesh and native tissue prolapse repairs
- Excision resolves pain ~50% of the time
- Possible confounder: reporting / identifying pain pre-op


Consider Physical Therapy

- Before Pelvic Reconstructive Surgery if patient has pain
- In conjunction with surgical management of post-operative pain

Voiding Dysfunction


<table>
<thead>
<tr>
<th>Persistent voiding dysfunction</th>
<th>Retropubic MUS</th>
<th>Trans-obturator MUS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.7%</td>
<td>2.4%</td>
</tr>
</tbody>
</table>
Voiding Dysfunction

- Retrospective of patients with voiding dysfunction who had Simple incision or Partial excision
  - ~10% persistent retention
    - 50% if new incontinence procedure included
  - 2% (simple) vs. 23% (partial) had repeat incontinence surgery

Review

- Surgical mesh around the vagina provides effective and long lasting treatments
  - But is still a developing story...
- Mesh exposure in the vagina often does not require intervention
- Surgical excision usually is effective for mesh exposure treatment
  - But some women require multiple surgeries

Review

- Mesh in the bladder or bowel
  - Avoid placing mesh over organ repair
  - Multi-disciplinary approach
- Pelvic pain / dyspareunia should be queried + treated before PFD surgery
- Simple sling incision > Partial excision for Tx of post-op voiding dysfunction

Questions?